

**IN THE UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF TEXAS  
MARSHALL DIVISION**

ACTAVIS LABORATORIES UT, INC.,

Plaintiff,

v.

UCB, INC.,

Defendant.

Case No. 2:15-cv-1001-JRG-RSP

**MEMORANDUM OPINION AND ORDER**

Before the Court is the opening claim construction brief of Actavis Laboratories UT, Inc. (“Plaintiff”) (Dkt. No. 46, filed on April 12, 2016),<sup>1</sup> the response of UCB, Inc. (“Defendant”) (Dkt. No. 49, filed on April 26, 2016), and the reply of Plaintiff (Dkt. No. 51, filed on May 4, 2016). The Court held a hearing on the issues of claim construction and claim definiteness on May 25, 2016. Having considered the arguments and evidence presented by the parties at the hearing and in their briefing, having considered the intrinsic evidence, and having made subsidiary factual findings about the extrinsic evidence, the Court hereby issues this Claim Construction Memorandum Opinion and Order. *See Phillips v. AWH Corp.*, 415 F.3d 1303, 1314 (Fed. Cir. 2005); *Teva Pharm. USA, Inc. v. Sandoz, Inc.*, 135 S. Ct. 831, 841 (2015).

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<sup>1</sup> Citations to the parties’ filings are to the filing’s number in the docket (Dkt. No.) and pin cites are to the page numbers assigned by ECF.

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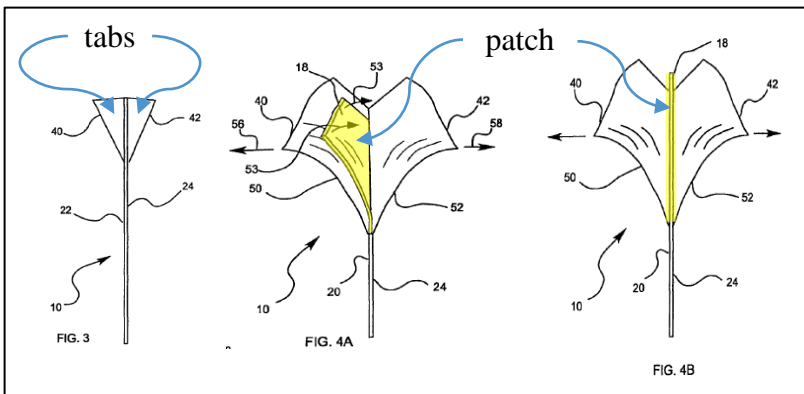
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## I. BACKGROUND

Plaintiff alleges infringement of U.S. Patent No. 7,921,999 (the “’999 Patent”). The ’999 Patent is entitled “Peelable Pouch For Transdermal Patch And Method For Packaging.” The application leading to the ’999 Patent was filed on December 21, 2006 and the patent issued on April 12, 2011. Through continuation-in-part and continuation applications, the ’999 Patent claims priority to a provisional application filed on December 20, 2001.

In general, the ’999 Patent is directed to packaging for a transdermal patch. Specifically, it is directed to packaging that addresses failings in the prior art related to: (1) tearing open the packages to access the transdermal patch, and (2) adherence of the transdermal patch to the packaging caused by leakage of the transdermal patch’s adhesive that is used to attach the patch to the skin. ’999 Patent col.1 ll.28–50. According to the parties, this leakage of adhesive is referred to as “cold flow.” (Dkt. No. 46 at 7; Dkt. No. 49 at 13). The ’999 Patent addresses these failings with a peel-open packaging having certain characteristics that enable the patch that adheres to the packaging to release from the packaging when the package is opened—the peelable pouch system.

The ’999 Patent’s packaging can be generally understood with reference to Figures 3, 4A, and 4B, reproduced here and annotated by the Court. These figures depict a side view of the pouch in various configurations: Figure 3 depicts the pouch as closed, Figure 4A depicts the pouch as partially opened, and Figure 4B depicts the pouch as opened. The pouch includes plies



(22, 24) that are sealed together to form a cavity. The patch (18, in yellow) is disposed within the cavity. Portions of the plies are left unsealed, and form tabs (40, 42). The pouch is opened by pulling the tabs apart, which separates the plies along the seal. If the patch adheres to one of the plies due to cold flow of the patch's adhesive, it will bend with the ply as the tab is pulled. But because the patch is more rigid (i.e. less flexible) than the ply, it resists bending more so than the ply and the patch will release from the ply without manipulation of the patch by the user. Because the patch is resilient, it will return to its original un-bent form when released from the ply.

The abstract of the '999 Patent provides:

A peelable pouch comprises a substantially flat enclosure formed by first and second opposing flexible plies. A seal extends along at least a portion of a perimeter of the opposing plies. A flat, flexible transdermal patch is disposed in the enclosure and includes a bioactive agent dissolved in a layer of adhesive. A release liner is removably attached over the layer of adhesive, with the patch and the release liner together being sufficiently resilient so as to generate a spring force when displaced out of the flat configuration. The first and the second plies each being separable along the seal and displaceable out of the flat configuration. The spring force generated by the patch and the release liner being sufficient to overcome an adhesive force created by the adhesive between the patch and one of the plies.

Claims 1 and 14, the '999 Patent's independent claims, recite as follows:

<p><b>1.</b> A peelable pouch system for holding a transdermal patch, comprising:</p> <ul style="list-style-type: none"> <li>a substantially flat enclosure formed by first and second opposing flexible plies in substantially flat configurations;</li> <li>a seal extending along at least a portion of a perimeter of the opposing plies and joining said plies to form the enclosure;</li> <li>a flat, flexible transdermal patch, disposed in the enclosure, the patch including an adhesive layer with a bioactive agent therein, the adhesive layer disposed between a backing layer and a removable release liner;</li> <li>the first and the second plies each being separable along the seal and displaceable out of the flat configuration when pulled apart to open the enclosure and expose the patch; and</li> <li>the patch being resilient so as to generate a spring force when displaced out of the flat configuration sufficient to overcome an adhesive force between the patch and one of the plies created by the adhesive layer leaking an adhesive onto one of the plies.</li> </ul>	<p><b>14.</b> A peelable pouch system for holding a transdermal patch, comprising:</p> <ul style="list-style-type: none"> <li>a substantially flat enclosure formed by first and second opposing flexible plies;</li> <li>a seal, extending along at least a portion of a perimeter of the opposing plies and coupling the plies to one another;</li> <li>a flat, flexible transdermal patch, disposed in the enclosure, the patch including an adhesive layer with a bioactive agent therein, the adhesive layer disposed between a backing layer and a removable release liner;</li> <li>the patch being rigid so as to at least partially resist bending and being resilient so as to return to a substantially flat orientation after being bent out of the flat configuration;</li> <li>the first and the second plies each being separable along the seal and displaceable out of the flat configuration.</li> </ul>
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## II. LEGAL PRINCIPLES

### A. Claim Construction

“It is a ‘bedrock principle’ of patent law that ‘the claims of a patent define the invention to which the patentee is entitled the right to exclude.’” *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005) (en banc) (quoting *Innova/Pure Water Inc. v. Safari Water Filtration Sys., Inc.*, 381 F.3d 1111, 1115 (Fed. Cir. 2004)). To determine the meaning of the claims, courts start by considering the intrinsic evidence. *Id.* at 1313; *C.R. Bard, Inc. v. U.S. Surgical Corp.*, 388 F.3d 858, 861 (Fed. Cir. 2004); *Bell Atl. Network Servs., Inc. v. Covad Commc’ns Group, Inc.*, 262 F.3d 1258, 1267 (Fed. Cir. 2001). The intrinsic evidence includes the claims themselves, the specification, and the prosecution history. *Phillips*, 415 F.3d at 1314; *C.R. Bard, Inc.*, 388 F.3d at 861. The general rule—subject to certain specific exceptions discussed *infra*—is that each claim term is construed according to its ordinary and accustomed meaning as understood by one of ordinary skill in the art at the time of the invention in the context of the patent. *Phillips*, 415 F.3d at 1312–13; *Alloc, Inc. v. Int’l Trade Comm’n*, 342 F.3d 1361, 1368 (Fed. Cir. 2003); *Azure Networks, LLC v. CSR PLC*, 771 F.3d 1336, 1347 (Fed. Cir. 2014) (“There is a heavy presumption that claim terms carry their accustomed meaning in the relevant community at the relevant time.”) (vacated on other grounds).

“The claim construction inquiry . . . begins and ends in all cases with the actual words of the claim.” *Renishaw PLC v. Marposs Societa’ per Azioni*, 158 F.3d 1243, 1248 (Fed. Cir. 1998). “[I]n all aspects of claim construction, ‘the name of the game is the claim.’” *Apple Inc. v. Motorola, Inc.*, 757 F.3d 1286, 1298 (Fed. Cir. 2014) (quoting *In re Hiniker Co.*, 150 F.3d 1362, 1369 (Fed. Cir. 1998)). First, a term’s context in the asserted claim can be instructive. *Phillips*, 415 F.3d at 1314. Other asserted or unasserted claims can also aid in determining the claim’s meaning, because claim terms are typically used consistently throughout the patent. *Id.*

Differences among the claim terms can also assist in understanding a term's meaning. *Id.* For example, when a dependent claim adds a limitation to an independent claim, it is presumed that the independent claim does not include the limitation. *Id.* at 1314–15.

“[C]laims ‘must be read in view of the specification, of which they are a part.’” *Id.* (quoting *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 979 (Fed. Cir. 1995) (en banc)). “[T]he specification ‘is always highly relevant to the claim construction analysis. Usually, it is dispositive; it is the single best guide to the meaning of a disputed term.’” *Id.* (quoting *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996)); *Teleflex, Inc. v. Ficoso N. Am. Corp.*, 299 F.3d 1313, 1325 (Fed. Cir. 2002). But, “[a]lthough the specification may aid the court in interpreting the meaning of disputed claim language, particular embodiments and examples appearing in the specification will not generally be read into the claims.” *Comark Commc’ns, Inc. v. Harris Corp.*, 156 F.3d 1182, 1187 (Fed. Cir. 1998) (quoting *Constant v. Advanced Micro-Devices, Inc.*, 848 F.2d 1560, 1571 (Fed. Cir. 1988)); *see also Phillips*, 415 F.3d at 1323. “[I]t is improper to read limitations from a preferred embodiment described in the specification—even if it is the only embodiment—into the claims absent a clear indication in the intrinsic record that the patentee intended the claims to be so limited.” *Liebel-Flarsheim Co. v. Medrad, Inc.*, 358 F.3d 898, 913 (Fed. Cir. 2004).

The prosecution history is another tool to supply the proper context for claim construction because, like the specification, the prosecution history provides evidence of how the U.S. Patent and Trademark Office (“PTO”) and the inventor understood the patent. *Phillips*, 415 F.3d at 1317. However, “because the prosecution history represents an ongoing negotiation between the PTO and the applicant, rather than the final product of that negotiation, it often lacks the clarity of the specification and thus is less useful for claim construction purposes.” *Id.* at

1318; *see also Athletic Alternatives, Inc. v. Prince Mfg.*, 73 F.3d 1573, 1580 (Fed. Cir. 1996) (ambiguous prosecution history may be “unhelpful as an interpretive resource”).

Although extrinsic evidence can also be useful, it is “less significant than the intrinsic record in determining the legally operative meaning of claim language.” *Phillips*, 415 F.3d at 1317 (quoting *C.R. Bard, Inc.*, 388 F.3d at 862). Technical dictionaries and treatises may help a court understand the underlying technology and the manner in which one skilled in the art might use claim terms, but technical dictionaries and treatises may provide definitions that are too broad or may not be indicative of how the term is used in the patent. *Id.* at 1318. Similarly, expert testimony may aid a court in understanding the underlying technology and determining the particular meaning of a term in the pertinent field, but an expert’s conclusory, unsupported assertions as to a term’s definition are entirely unhelpful to a court. *Id.* Generally, extrinsic evidence is “less reliable than the patent and its prosecution history in determining how to read claim terms.” *Id.* The Supreme Court recently explained the role of extrinsic evidence in claim construction:

In some cases, however, the district court will need to look beyond the patent’s intrinsic evidence and to consult extrinsic evidence in order to understand, for example, the background science or the meaning of a term in the relevant art during the relevant time period. *See, e.g., Seymour v. Osborne*, 11 Wall. 516, 546 (1871) (a patent may be “so interspersed with technical terms and terms of art that the testimony of scientific witnesses is indispensable to a correct understanding of its meaning”). In cases where those subsidiary facts are in dispute, courts will need to make subsidiary factual findings about that extrinsic evidence. These are the “evidentiary underpinnings” of claim construction that we discussed in *Markman*, and this subsidiary factfinding must be reviewed for clear error on appeal.

*Teva Pharm. USA, Inc. v. Sandoz, Inc.*, 135 S. Ct. 831, 841 (2015).

## **B. Departing from the Ordinary Meaning of a Claim Term**

There are “only two exceptions to [the] general rule” that claim terms are construed according to their plain and ordinary meaning: “1) when a patentee sets out a definition and acts

as his own lexicographer, or 2) when the patentee disavows the full scope of the claim term either in the specification or during prosecution.”<sup>2</sup> *Golden Bridge Tech., Inc. v. Apple Inc.*, 758 F.3d 1362, 1365 (Fed. Cir. 2014) (quoting *Thorner v. Sony Computer Entm’t Am. LLC*, 669 F.3d 1362, 1365 (Fed. Cir. 2012)); *see also GE Lighting Solutions, LLC v. AgiLight, Inc.*, 750 F.3d 1304, 1309 (Fed. Cir. 2014) (“[T]he specification and prosecution history only compel departure from the plain meaning in two instances: lexicography and disavowal.”). The standards for finding lexicography or disavowal are “exacting.” *GE Lighting Solutions*, 750 F.3d at 1309.

To act as his own lexicographer, the patentee must “clearly set forth a definition of the disputed claim term,” and “clearly express an intent to define the term.” *Id.* (quoting *Thorner*, 669 F.3d at 1365); *see also Renishaw*, 158 F.3d at 1249. The patentee’s lexicography must appear “with reasonable clarity, deliberateness, and precision.” *Renishaw*, 158 F.3d at 1249.

To disavow or disclaim the full scope of a claim term, the patentee’s statements in the specification or prosecution history must amount to a “clear and unmistakable” surrender. *Cordis Corp. v. Boston Sci. Corp.*, 561 F.3d 1319, 1329 (Fed. Cir. 2009); *see also Thorner*, 669 F.3d at 1366 (“The patentee may demonstrate intent to deviate from the ordinary and accustomed meaning of a claim term by including in the specification expressions of manifest exclusion or restriction, representing a clear disavowal of claim scope.”) “Where an applicant’s statements are amenable to multiple reasonable interpretations, they cannot be deemed clear and unmistakable.” *3M Innovative Props. Co. v. Tredegar Corp.*, 725 F.3d 1315, 1326 (Fed. Cir. 2013).

Although a statement of lexicography or disavowal must be exacting and clear, it need not be “explicit.” *See Trs. of Columbia Univ. v. Symantec Corp.*, 811 F.3d 1359, 1364 (Fed. Cir.

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<sup>2</sup> Some cases have characterized other principles of claim construction as “exceptions” to the general rule, such as the statutory requirement that a means-plus-function term is construed to cover the corresponding structure disclosed in the specification. *See, e.g., CCS Fitness, Inc. v. Brunswick Corp.*, 288 F.3d 1359, 1367 (Fed. Cir. 2002).

2016) (“a patent applicant need not expressly state ‘my invention does not include X’ to indicate his exclusion of X from the scope of his patent”). Lexicography or disavowal can be implied where, *e.g.*, the patentee makes clear statements characterizing the scope and purpose of the invention. *See On Demand Mach. Corp. v. Ingram Indus., Inc.*, 442 F.3d 1331, 1340 (Fed. Cir. 2006) (“[W]hen the scope of the invention is clearly stated in the specification, and is described as the advantage and distinction of the invention, it is not necessary to disavow explicitly a different scope.”). Nonetheless, the plain meaning governs “[a]bsent implied or explicit lexicography or disavowal.” *Trs. of Columbia Univ.*, 811 F.3d at 1364 n.2.

**C. Functional Claiming and 35 U.S.C. § 112, ¶ 6 (pre-AIA) / § 112(f) (AIA)**<sup>3</sup>

A patent claim may be expressed using functional language. *See* 35 U.S.C. § 112, ¶ 6; *Williamson v. Citrix Online, LLC*, 792 F.3d 1339, 1347–49 & n.3 (Fed. Cir. 2015) (*en banc* in relevant portion). Section 112, Paragraph 6, provides that a structure may be claimed as a “means . . . for performing a specified function” and that an act may be claimed as a “step for performing a specified function.” *Masco Corp. v. United States*, 303 F.3d 1316, 1326 (Fed. Cir. 2002).

But § 112, ¶ 6 does not apply to all functional claim language. There is a rebuttable presumption that § 112, ¶ 6 applies when the claim language includes “means” or “step for” terms, and that it does not apply in the absence of those terms. *Masco Corp.*, 303 F.3d at 1326; *Williamson*, 792 F.3d at 1348. The presumption stands or falls according to whether one of ordinary skill in the art would understand the claim with the functional language, in the context of the entire specification, to denote sufficiently definite structure or acts for performing the function. *See Media Rights Techs., Inc. v. Capital One Fin. Corp.*, 800 F.3d 1366, 1372 (Fed. Cir. 2015) (§ 112, ¶ 6 does not apply when “the claim language, read in light of the specification,

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<sup>3</sup> Because the application resulting in the ’999 Patent was filed before September 16, 2012, the effective date of the America Invents Act (“AIA”), the Court refers to the pre-AIA version of § 112.

recites sufficiently definite structure” (quotation marks omitted) (citing *Williamson*, 792 F.3d at 1349; *Robert Bosch, LLC v. Snap-On Inc.*, 769 F.3d 1094, 1099 (Fed. Cir. 2014))); *Williamson*, 792 F.3d at 1349 (§ 112, ¶ 6 does not apply when “the words of the claim are understood by persons of ordinary skill in the art to have sufficiently definite meaning as the name for structure”); *Masco Corp.*, 303 F.3d at 1326 (§ 112, ¶ 6 does not apply when the claim includes an “act” corresponding to “how the function is performed”); *Personalized Media Communications, L.L.C. v. International Trade Commission*, 161 F.3d 696, 704 (Fed. Cir. 1998) (§ 112, ¶ 6 does not apply when the claim includes “sufficient structure, material, or acts within the claim itself to perform entirely the recited function . . . even if the claim uses the term ‘means.’” (quotation marks and citation omitted)).

When it applies, § 112, ¶ 6 limits the scope of the functional term “to only the structure, materials, or acts described in the specification as corresponding to the claimed function and equivalents thereof.” *Williamson*, 792 F.3d at 1347. Construing a means-plus-function limitation involves multiple steps. “The first step . . . is a determination of the function of the means-plus-function limitation.” *Medtronic, Inc. v. Advanced Cardiovascular Sys., Inc.*, 248 F.3d 1303, 1311 (Fed. Cir. 2001). “[T]he next step is to determine the corresponding structure disclosed in the specification and equivalents thereof.” *Id.* A “structure disclosed in the specification is ‘corresponding’ structure only if the specification or prosecution history clearly links or associates that structure to the function recited in the claim.” *Id.* The focus of the “corresponding structure” inquiry is not merely whether a structure is capable of performing the recited function, but rather whether the corresponding structure is “clearly linked or associated with the [recited] function.” *Id.* The corresponding structure “must include all structure that actually performs the recited function.” *Default Proof Credit Card Sys. v. Home Depot U.S.A., Inc.*, 412 F.3d 1291,

1298 (Fed. Cir. 2005). However, § 112 does not permit “incorporation of structure from the written description beyond that necessary to perform the claimed function.” *Micro Chem., Inc. v. Great Plains Chem. Co.*, 194 F.3d 1250, 1258 (Fed. Cir. 1999).

For § 112, ¶ 6 limitations implemented by a programmed general purpose computer or microprocessor, the corresponding structure described in the patent specification must include an algorithm for performing the function. *WMS Gaming Inc. v. Int’l Game Tech.*, 184 F.3d 1339, 1349 (Fed. Cir. 1999). The corresponding structure is not a general purpose computer but rather the special purpose computer programmed to perform the disclosed algorithm. *Aristocrat Techs. Austl. Pty Ltd. v. Int’l Game Tech.*, 521 F.3d 1328, 1333 (Fed. Cir. 2008).

**D. Definiteness Under 35 U.S.C. § 112, ¶ 2 (pre-AIA) / § 112(b) (AIA) <sup>4</sup>**

Patent claims must particularly point out and distinctly claim the subject matter regarded as the invention. 35 U.S.C. § 112, ¶ 2. A claim, when viewed in light of the intrinsic evidence, must “inform those skilled in the art about the scope of the invention with reasonable certainty.” *Nautilus Inc. v. Biosig Instruments, Inc.*, 134 S. Ct. 2120, 2129 (2014). If it does not, the claim fails § 112, ¶ 2 and is therefore invalid as indefinite. *Id.* at 2124. Whether a claim is indefinite is determined from the perspective of one of ordinary skill in the art as of the time the application for the patent was filed. *Id.* at 2130. As it is a challenge to the validity of a patent, the failure of any claim in suit to comply with § 112 must be shown by clear and convincing evidence. *Id.* at 2130 n.10. “[I]ndefiniteness is a question of law and in effect part of claim construction.” *ePlus, Inc. v. Lawson Software, Inc.*, 700 F.3d 509, 517 (Fed. Cir. 2012).

When a term of degree is used in a claim, “the court must determine whether the patent provides some standard for measuring that degree.” *Biosig Instruments, Inc. v. Nautilus, Inc.*,

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<sup>4</sup> Because the application resulting in the ’999 Patent was filed before September 16, 2012, the effective date of the America Invents Act (“AIA”), the Court refers to the pre-AIA version of § 112.

783 F.3d 1374, 1378 (Fed. Cir. 2015) (quotation marks omitted). Likewise, when a subjective term is used in a claim, “the court must determine whether the patent’s specification supplies some standard for measuring the scope of the [term].” *Datamize, LLC v. Plumtree Software, Inc.*, 417 F.3d 1342, 1351 (Fed. Cir. 2005); *accord Interval Licensing LLC v. AOL, Inc.*, 766 F.3d 1364, 1371 (Fed. Cir. 2014) (citing *Datamize*, 417 F.3d at 1351).

In the context of a claim governed by 35 U.S.C. § 112, ¶ 6, the claim is invalid as indefinite if the claim fails to disclose adequate corresponding structure to perform the claimed functions. *Williamson*, 792 F.3d at 1351–52. The disclosure is inadequate when one of ordinary skill in the art “would be unable to recognize the structure in the specification and associate it with the corresponding function in the claim.” *Id.* at 1352.

### **III. PERSON OF ORDINARY SKILL IN THE ART**

Defendant posits that one of ordinary skill in the relevant art is: “a person with a Ph.D. degree or the equivalent work experience in a field relating to polymer sciences as well as several years of experience designing or developing transdermal delivery systems.” (Dkt. No. 49 at 14 n.3); (Declaration of David J. Ensore, Ph.D (“Ensore Decl.”) ¶ 26, Dkt. No. 49-6 at 7–8).

Plaintiff disagrees with Defendant’s characterization of one of ordinary skill in the art, and posits that artisan is: “a person with a master’s degree in mechanical engineering or packaging, or equivalent professional experience, as well as at least two years of experience in the design and use of packaging for transdermal patches or other medical devices or pharmaceuticals.” (Dkt. No. 51 at 5–6); (Declaration of J. Paul Singh, Ph.D (“Singh Decl.”) ¶¶ 25–28, Dkt. No. 51-2 at 6–7). Plaintiff contends that Defendant’s representation of one of ordinary skill in the art is flawed because it is based on an incorrect view of the art. (Dkt. No. 51 at 5); (Singh Decl. ¶¶ 26–27, Dkt. No. 51-2 at 7). Plaintiff contends that the art is transdermal-

patch packaging, not transdermal delivery systems or polymer science. (Dkt. No. 51 at 5); (Singh Decl. ¶¶ 26–27, Dkt. No. 51-2 at 7).

The Court tends to agree with Plaintiff. The '999 Patent states the field of the invention as: “peelable pouches for storage of transdermal patches, and methods for packaging objects or transdermal patches.” '999 Patent col.1 ll.15–17. This is packaging, not delivery. As such, it is unlikely that one of skill in the art requires specialized knowledge in polymers or transdermal drug delivery.

However, the Court determines that the dispute is moot. The Court’s findings and holdings regarding the claim construction disputes between the parties are the same whether it applies Plaintiff’s or Defendant’s proposed definition of one of skill in the art.<sup>5</sup> The Court therefore declines to rule on this dispute at this time.

#### IV. CONSTRUCTION OF DISPUTED TERMS

The parties’ positions and the Court’s analysis as to the disputed terms are presented below.

##### A. The Flexible/Rigid Terms

Disputed Term <sup>6</sup>	Plaintiff’s Proposed Construction	Defendant’s Proposed Construction
“flexible” <ul style="list-style-type: none"><li>• '999 Patent Claims 1, 14</li></ul>	Plain and ordinary meaning.	Indefinite.
“relatively more rigid” <ul style="list-style-type: none"><li>• '999 Patent Claims 2, 16</li></ul>	Plain and ordinary meaning.	Indefinite.

<sup>5</sup> Moreover, this is likely a fact question for the jury. *Cf. MobileMedia Ideas LLC v. Apple Inc.*, 780 F.3d 1159, 1167 (Fed. Cir. 2015) (in the context of obviousness, “the level of ordinary skill in the field of the invention” is a jury fact question reviewed for substantial evidence).

<sup>6</sup> For all term charts in this Order, the claims in which the term is found are listed with the term but: (1) only the highest level claim in each dependency chain is listed, and (2) only asserted claims identified in the Parties’ Joint Claim Construction Chart (Dkt. No. 52) are listed.

<b>Disputed Term<sup>6</sup></b>	<b>Plaintiff's Proposed Construction</b>	<b>Defendant's Proposed Construction</b>
“rigid so as to at least partially resist bending” <ul style="list-style-type: none"> <li>• ’999 Patent Claim 14</li> </ul>	Plain and ordinary meaning.	Indefinite.

Because the parties’ arguments and proposed constructions with respect to these terms are related, the Court addresses the terms together.

### **The Parties’ Positions**

Plaintiff submits that “flexible” is used in the patent to denote that something may be bent without breaking, as per the term’s ordinary meaning. (Dkt. No. 46 at 14). Plaintiff further submits that the patent allows that something may be simultaneously “flexible” and “rigid” and “resilient” in that flexible material, while bendable, may resist the bend and return to its unbent position when no longer being bent. (*Id.* at 14–15) (citing U.S. Patent App. No. 10/321,405<sup>7</sup> (the “’405 App.”) File Wrapper April 2, 2004 Response/Amendment at 9, Dkt. No. 46-4 at 4).

Plaintiff submits that “relatively more rigid” is not indefinite because “rigid,” as used in the patent, does not mean absolutely inflexible—it is used in the patent to denote that materials have degrees of rigidity. (*Id.* at 15–16). For example, the patent teaches there is a “difference in rigidity between the patch and the ply.” (*Id.* at 16) (quoting ’999 Patent col.10 ll.12–15). And, Plaintiff submits, the claim language provides the measure of “relative” in that it states “the release liner of the patch is relatively more rigid than the remaining portions of the patch.” (*Id.*). According to Plaintiff, this means that “the rigidity of the release liner of the patch is measured relative to the rigidity of the remaining portions of the patch.” (*Id.* at 16–17).

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<sup>7</sup> The ’999 Patent claims priority to the ’405 application. ’999 Patent at [63] Related U.S. Application Data.

Plaintiff submits that “rigid so as to a least partially resist bending” is readily understood in the context of the patent’s teaching regarding the rigidity of the patch causing “a restoring spring force” when the patch is bent. (*Id.* at 17) (quoting ’999 Patent col.10 ll.12–19).

In addition to the claims themselves, Plaintiff cites the following intrinsic and extrinsic evidence to support its position. **Intrinsic evidence:** ’999 Patent col.9 ll.3–5, col.9 ll.56–62, col.10 ll.12–19, figs. 4A, 4B; ’405 App. File Wrapper April 2, 2004 Response/Amendment (excerpts) (Plaintiff’s Ex. D, Dkt. No. 46-4). **Extrinsic evidence:** *Random House Dictionary of the English Language* (1987) “flexible” (Plaintiff’s Ex. C, Dkt. No. 46-3).

Defendant responds that it is impossible for a material to be simultaneously “flexible” and “rigid” and that, therefore, the claims of the ’999 Patent are indefinite because they call for a patch that is both flexible and rigid. (Dkt. No. 49 at 19–20). This, according to Defendant, is because “rigid” is the antonym of “flexible.” (*Id.*). Defendant further responds that the patent does not provide any guidance as to how the patch could be both flexible and rigid. (*Id.* at 20–21). Defendant contends that the patent’s discussion of the patch being “flexible” to conform to the contours of the user’s body is inapposite because the patch in the package is not the same patch that is on the skin, the packaged patch includes a release liner. (*Id.* at 20–21). Further, Defendant contends that the patent’s discussion of the patch’s ability to return to its original form after being bent does not provide any metric to determine a degree of rigidity but rather pertains to the patch’s resilience. (*Id.* at 21). And, according to Defendant, in the prosecution of the ’999 Patent, the patent examiner previously found that rigidity defined by its sufficiency to return the patch to its pre-bend form is indefinite—and that finding occurred under a less-stringent pre-*Nautilus* standard. (*Id.* at 21–22).

With respect to “relatively more rigid,” Defendant responds that the relative nature of the rigidity here exacerbates the flexible/rigid indefiniteness issue because the meaning of “relative” is uncertain as a term of degree and because it is unclear whether the release liner is “relatively more rigid” than the remaining portions of the patch separately or together, or to one or both of the remaining portions. (*Id.* at 22–23).

With respect to “rigid so as to at least partially resist bending,” Defendant responds that “[v]irtually every material can be said to resist bending to some extent depending on the circumstances” and the patent fails to provide any guidance as to what level of resistance satisfies the claim language. (*Id.* at 23) (citing Ensore Decl. ¶ 45, Dkt. No.49-6 at 12). Defendant further responds that the term “partially” is subjective, and therefore indefinite. (*Id.* at 24). Defendant argues that determining whether a material is “rigid so as to at least partially resist bending” based on the material’s tendency to return to its pre-bend configuration improperly conflates two claim terms, “rigid” and “resilient.” (*Id.* at 24–25). And Defendant argues that determining whether a material is “rigid so as to at least partially resist bending” based on the “restoring spring force” generated by the material when bent improperly renders Claim 15 superfluous. (*Id.* at 25–26).

In addition to the claims themselves, Defendant cites the following intrinsic and extrinsic evidence to support its position. **Intrinsic evidence:** ’999 Patent col.10 ll.6–19, fig.6; ’999 Patent File Wrapper Jan. 20, 2010 Response to Restriction Requirement (Defendant’s Ex. E, Dkt. No. 49-5), May 27, 2010 Office Action (Defendant’s Ex. A, Dkt. No. 49-1), Oct. 27, 2010 Amendment (Defendant’s Ex. C, Dkt. No. 49-3). **Extrinsic evidence:** *Merriam Webster’s Collegiate Thesaurus* (1993) “rigid” (Defendant’s Ex. D, Dkt. No. 49-4); Ensore Decl. (Dkt.

No. 49-6); *Random House Dictionary of the English Language* (1987) “flexible” (Plaintiff’s Ex. C, Dkt. No. 46-3).

Plaintiff replies that that the claims themselves provide the standard by which to determine whether a patch is both “flexible” and “rigid.” (Dkt. No. 51 at 8–10). With respect to Claims 2 and 16, Plaintiff contends they recite a simple comparison of the rigidity of different materials—which is readily done by comparing the materials’ “deformation in response to loading or strain.” (*Id.* at 9) (citing Singh Decl. ¶ 40, Dkt. No. 51-2 at 11). With respect to Claim 14, Plaintiff contends that the “rigid” and “resilient” properties work together to define that the patch partially resists bending with the plies and returns to a substantially flat form after bending with the plies. (*Id.* at 9–10) (citing Singh Decl. ¶ 39, Dkt. No. 51-2 at 10).

Plaintiff cites further **extrinsic evidence** to support its position: Singh Decl. (Dkt. No. 51-2).

### **Analysis**

The dispute essentially revolves around the meaning of “rigid.” The Court understands “rigid,” as it is used in the ’999 Patent, to denote something that is resistant to flexing—it is not used to denote something that is necessarily absolutely inflexible. Given this understanding of “rigid,” Defendant has failed prove that any claim is indefinite because of the Flexible/Rigid terms.

The Court understands that “rigid” and “rigidity” are used in the ’999 Patent to denote the ease with which a flexible object may be bent. As Plaintiff contends, something is “flexible” if it can bend without breaking. Defendant does not dispute this. But not everything that is flexible is as easily bent. *See, e.g., Random House Dictionary of the English Language* (1987), (Dkt. No. 46-3 at 3) (noting a difference between “flexible” and its synonyms based on the “ease in

bending”). That is, some flexible things are more easily bent than are other flexible things. Put another way, some flexible things resist bending more than do other flexible things. The patent expresses this ease-of-bending concept as “rigidity.” *See, e.g.*, ’999 Patent col.9 ll.51–67 (noting that “the plies 22, 24 can be more flexible (or more easily bent) than the patch by itself” and that plies bend “in a direction along the plane of the patch 18 where the patch is *most rigid*” (emphasis added)); col.10 ll.12–13 (noting “the *difference in rigidity* between the patch and the ply” (emphasis added)); col.10 ll.21–24 (noting that the material of the patch “is selected to provide *sufficient rigidity*” (emphasis added))).

That the patent is not using “rigid” in the sense of absolutely inflexible is also apparent from a plain reading of the claims. For example, Claim 2 recites that the “release liner is relatively more rigid than remaining portions of the patch.” Here, the term “relatively” clarifies that the claim is not referring to absolute rigidity. The rest of the term describes that the release liner is less flexible than what remains of the patch once the “removable release liner” is removed. Similarly, Claim 14 recites “the patch being rigid so as to at least partially resist bending.” The Court finds that “partially” here is not a subjective term as Defendant contends. Rather, “so as to at least partially resist bending” provides guidance as to the patch’s rigidity. The plain meaning of “the patch being rigid so as to at least partially resist bending” in the context of the claim is that while the patch can be bent—i.e., it is not inflexible—it resists the bending. And while this limitation may, as Defendant contends, be broad, breadth is not indefiniteness.

Accordingly, the Court determines that “flexible” has its plain and ordinary meaning and construes “relatively more rigid” and “rigid so as to at least partially resist bending” as follows:

- “relatively more rigid” means “more resistant to bending”; and

- “rigid so as to at least partially resist bending” means “at least partially resistant to bending.”

## **B. The Spring Force/Adhesive Force Terms**

<b>Disputed Term</b>	<b>Plaintiff’s Proposed Construction</b>	<b>Defendant’s Proposed Construction</b>
“resilient so as to generate a spring force when displaced out of the flat configuration sufficient to overcome an adhesive force between the patch and one of the plies created by the adhesive layer leaking an adhesive onto one of the plies” <ul style="list-style-type: none"> <li>• ’999 Patent Claim 1</li> </ul>	Plain and ordinary meaning.	Indefinite.
“the patch generates a spring force when bent out of the flat configuration, the spring force being sufficient to overcome an adhesive force between the patch and one of the plies created by a portion of the adhesive” <ul style="list-style-type: none"> <li>• ’999 Patent Claim 15</li> </ul>	Plain and ordinary meaning.	Indefinite.

Because the parties’ arguments and proposed constructions with respect to these terms are related, the Court addresses the terms together.

### **The Parties’ Positions**

Plaintiff submits that these limitations are directed to the “element of the invention that allows the patch to become unstuck from the plies of the pouch.” (Dkt. No. 46 at 21). The patent explains that because the patch’s adhesive may escape from the patch, the patch “may adhere to the interior of the [pouch]” and thereby make it difficult to retrieve the patch from the pouch. (*Id.* at 21–22) (quoting ’999 Patent col.8 ll.24–32). Thus, if the patch adheres to a ply, it will bend

along with the ply when the pouch is opened. (*Id.* at 22) (citing '999 Patent col.10 ll.9–12, fig.4A). In response to this bending, the patch will generate a spring force that is directed opposite the bending and that is sufficient to overcome the adhesive force, and the patch will “peel away from the ply” to which it adhered. (*Id.* at 22) (quoting '999 Patent col.10 ll.12–19). According to Plaintiff, the adhesive force that must be overcome is a function of various factors that contribute to the leakage of adhesive—but these factors are known to those of ordinary skill in the art such that they know “the range of sticking to expect under normal shipping and handling conditions based on industry standards.” (*Id.* at 23).

In addition to the claims themselves, Plaintiff cites the following **intrinsic evidence** to support its position: '999 Patent col.8 ll.24–49, col.9 ll.52–56, col.10 ll.9–28, figs.4A, 4B.

Defendant responds that the “adhesive force” by which the patch is bound to a ply varies considerably in practice and nothing in the patent provides guidance as to how and when to determine the force. (Dkt. No. 49 at 13–14). Defendant argues that a given patch may at one time not adhere to a ply (and therefore be outside the scope of the claims), at a later time be bound to a ply because of intervening leakage of adhesive (cold flow) but with an adhesive force lower than the spring force (and therefore potentially within the scope of the claims), and at a yet later time and with more intervening leakage of adhesive be bound to a ply with an adhesive force greater than the spring force (and therefore be outside the scope of the claims). (*Id.* at 14–15). Thus, Defendant concludes, there is no standard by which to analyze whether a patch is within the scope of the claims. (*Id.* at 15).

Defendant further responds that a standard by which the spring force is sufficient to overcome the adhesive force in “an acceptable percentage of transdermal systems” based on “a range of sticking to expect under normal shipping and handling conditions based on industry

standards” is untenable. (*Id.* at 15–16) (quoting Plaintiff’s Brief, Dkt. No. 46 at 23). Defendant contends that such a standard is improperly vague at least with respect to the “range of sticking,” “normal shipping and handling conditions,” “industry standards,” and “acceptable percentage.” (*Id.* at 16–17).

Defendant also responds that Claims 1 and 15 are indefinite because they are apparatus claims that include methods steps. (*Id.* at 17–18). Specifically, Defendant contends that because the only way to determine whether the spring force is sufficient to overcome the adhesive force is to displace or bend the patch, Claim 1 requires the user to “conduct the step of displacing the patch” and Claim 15 requires the user to “bend the patch.” (*Id.* at 18).

In addition to the claims themselves, Defendant cites the following intrinsic and extrinsic evidence to support its position. **Intrinsic evidence:** ’999 File wrapper Oct. 27, 2010 Amendment (Defendant’s Ex. C, Dkt. No. 49-3). **Extrinsic evidence:** Ensore Decl. (Dkt. No. 49-6).

Plaintiff replies that the pouch system claimed in the ’999 Patent has recited properties that result in it functioning in a certain way under certain conditions—the claims do not require that those conditions exist at all times, or ever. (Dkt. No. 51 at 6–7). And the claims do not require that the pouch actually perform the function it is capable of performing. (*Id.* at 8). Specifically, the claims do not require that the adhesive actually leak from the patch to bind the patch to a ply. (*Id.*). Rather, the claims require that if the adhesive leaks from the patch to bind the patch to a ply, the pouch system has the recited properties that would release the patch from the ply when the pouch is opened. (*Id.*). According to Plaintiff, the adhesive and spring forces of the claims are a function of factors “routinely addressed when designing and testing packaged products.” (*Id.* at 7–8) (citing Singh Decl. § III.D.2, Dkt. No. 51-2 at 10–11). That is, the pouch

system properties are such that it “will work across the range conditions expected and specified for the product.” (*Id.* at 3–4) (citing Singh Decl. ¶ 19, Dkt. No. 51-2 at 5).

Plaintiff cites further **extrinsic evidence** to support its position: Singh Decl. (Dkt. No. 51-2).

### **Analysis**

There are two disputes with respect to these terms. First, whether it is reasonably certain what it means for the “spring force . . . sufficient to overcome an adhesive force between the patch and one of the plies.” And second, whether the apparatus claims require the user to displace or bend the patch. As to the first, the Court determines that the meaning of the claim language is reasonably certain. As to the second, the Court determines that the claims are directed to capability, and do not require any act by the user. Defendant has failed prove that any claim is indefinite because of the Spring Force/Adhesive Force terms.

The plain meaning of “spring force being sufficient to overcome an adhesive force between the patch and one of the plies” is apparent from the words of the claim. The spring force is stronger than the adhesive force between the patch and one of the plies such that the bond between the patch and ply is broken by the spring force.

The patent provides further guidance regarding the degrees of spring force and adhesive force contemplated. Specifically, the patent describes that the spring force is of such a degree so as to overcome the adhesive force and spring free of the ply when the pouch holding the patch is opened. *See, e.g.*, ’999 Patent col.10 ll.15–19 (“The spring force is sufficient to cause the patch (together with the liner) to peel away from the ply (that is being held by fingers of the user), resulting in the patch being presented, in a ‘free’ state, for removal by the user from between the plies.”). Further, the patent describes that the adhesive force is due to the adhesive on the

transdermal patch—a special adhesive used to bond the patch to the skin so as to deliver the drug through the skin. *See, e.g., id.* at col.4 ll.15–18 (defining “transdermal patch” as a “delivery device which is used to transdermally deliver defined doses of a substance”), col.7 ll.23–62 (describing the “adhesive” as a “pharmaceutically acceptable carrier” and describing various acceptable carrier materials), col.8 ll.24–48 (describing that “a minimal amount of the adhesive [may] escape . . . [and] cause the patch to adhere to the interior of the packaging”); *see also*, ’999 Patent File Wrapper Oct. 27, 2010 Amendment at 9–10, (Dkt. No. 46-2 at 10–11) (noting that “when matrix patches are stored in pouches, some of the adhesive from the adhesive layer may leak or seep out onto the pouch. Therefore, when the pouch is opened, the matrix patch is adhered to the pouch.”). That is, the spring force is meant to overcome the adhesive force a user might experience when attempting to extract the patch from the pouch, not just any adhesive force. In the context of the patent, the Court understands that what a user might experience is a function of the storage and shipping conditions of the packaged transdermal patch—and the Court finds that it is reasonably certain that these conditions are the prescribed conditions of the packaged product. Singh Decl. ¶¶ 15–22, (Dkt. No. 51-2 at 6–8). Thus, the spring force is sufficient to overcome the adhesive force that might occur under this prescribed range of storage and shipping conditions. Whether a particular transdermal patch package satisfies these limitations is an issue of infringement, not of claim construction.

Further, the Court understands that terms are directed to capabilities of the pouch, rather than an actual use of the pouch. That is, the pouch is defined in part by the function it would perform under specific conditions—its capability. This is an acceptable patent claim structure. *UltimatePointer, L.L.C. v. Nintendo Co.*, 816 F.3d 816, 826 (Fed. Cir. 2016). The Federal Circuit recently reiterated in *UltimatePointer* that “[i]f an apparatus claim ‘is clearly limited to a[n

apparatus] possessing the recited structure and **capable** of performing the recited functions,’ then the claim is not invalid as indefinite.” *Id.* (quoting *Microprocessor Enhancement Corp. v. Texas Instruments Inc.*, 520 F.3d 1367, 1375 (Fed. Cir. 2008)) (emphasis in original). *Microprocessor Enhancement* is instructive. The limitation at issue there is “the conditional execution decision logic pipeline stage, when specified by the conditional execution specifier, determining the enable-write using the boolean algebraic evaluation.” *Microprocessor Enhancement*, 520 F.3d at 1371–72, 1375. That is, the *Microprocessor Enhancement* claim is directed to a particular structure (the “conditional execution decision logic pipeline stage”) that performs a certain function (“determining the enable-write using the boolean algebraic evaluation”) when a particular condition is met (“when specified by the conditional execution specifier”). *Id.* The Federal Circuit held that such a limitation is directed to the capability of a structure. The limitation was not directed to a step of performing the function or the particular condition in which the function is performed. *Id.* Thus the claim was not indefinite. *Id.* The claim language at issue here, taken in the context of the claim, is likewise directed to the capability of a structure—it is directed to the patch’s ability to generate a spring force to overcome an adhesive force in certain conditions.

Accordingly, the Court holds that these terms do not render any claim indefinite and determines that they have their plain and ordinary meaning and need no further construction.

C. “resilient so as to return to a substantially flat orientation after being bent out of the flat configuration”

Disputed Term	Plaintiff’s Proposed Construction	Defendant’s Proposed Construction
“resilient so as to return to a substantially flat orientation after being bent out of the flat configuration”  • ’999 Patent Claim 14	Plain and ordinary meaning.	Indefinite.

**The Parties’ Positions**

Plaintiff submits that, in the patent, a material is “resilient” when it develops a spring force in opposition to any bending of the material, such as to restore the material to its unbent position. (Dkt. No. 46 at 19) (citing ’405 App. File Wrapper at 9 (Dkt. No. 46-4 at 4)). Plaintiff further submits that “substantially flat orientation” is understood in the context of the patent’s teaching regarding the term “substantially.” (*Id.* at 19–20). Specifically, the patent explains that “substantially” “refers to the complete or nearly complete extent” of a property such that effect of the property is the “same overall result as if absolute and total completion were obtained.” (*Id.*) (quoting ’999 Patent col.5 ll.45–54). According to Plaintiff, the patent teaches that patch is “bent out of the flat configuration” when it is bent “along with the ply” when the pouch is opened by the use. (*Id.*) (quoting ’999 Patent col.10 ll.9–12).

In addition to the claims themselves, Plaintiff cites the following **intrinsic evidence** to support its position: ’999 Patent col.5 ll.45–54, col.10 ll.9–12, figs.4A, 4B; ’405 App. File Wrapper April 2, 2004 Response/Amendment (excerpts) (Plaintiff’s Ex. D, Dkt. No. 46-4).

Defendant responds that the scope of this term is indefinite for two reasons: First, it is unclear whether the patch must return to its substantially flat orientation regardless of how much it is bent or whether a patch that returns to substantially flat orientation after a small bend but not

after a large bend would satisfy the claims. (Dkt. No. 49 at 26). Second, it is unclear what level of flatness constitutes “substantially flat.” (*Id.* at 27–28).

Defendant also responds that Claim 14 is indefinite because it is an apparatus claim that includes methods steps. (*Id.* at 28). According to Defendant, to determine whether something falls within the scope of the claim, the patch must actually be bent and thus the claim includes a bending step. (*Id.*)

In addition to the claims themselves, Defendant cites the following intrinsic and extrinsic evidence to support its position. **Intrinsic evidence:** ’999 Patent col.5 ll.45–54. **Extrinsic evidence:** Ensore Decl. (Dkt. No. 49-6).

Plaintiff replies that the recited “bent out of the flat configuration” is the bending of the patch that occurs when the plies are bent if the patch adheres to a ply. (Dkt. No. 51 at 10). Plaintiff notes that the recited “enclosure” that houses the patch is “substantially flat,” and that Defendant does not contend that the “enclosure” term is indefinite. (*Id.*). Plaintiff contends that one of ordinary skill in the art would understand that the pouch and patch need not be perfectly flat. (*Id.*). Finally, Plaintiff argues as it did for the “spring force” and “adhesive force” limitations—the claims are directed to features of the pouch system, not to steps for operating the system. (*Id.*).

Plaintiff cites further **extrinsic evidence** to support its position: Singh Decl. (Dkt. No. 51-2).

### **Analysis**

The dispute over this term involves three issues. First, whether the meaning of “substantially flat” is reasonably certain. Second, whether it is reasonably certain how much bending the patch can experience and still be resilient. And third, whether the term incorporates a

method step into an apparatus claim. As to the first, the '999 Patent's guidance regarding the packaging and shipping benefits of a flat patch renders the meaning of "substantially flat" reasonably certain. As to the second, the bending that the patch must be able to return from is the bending due to the peeling of the ply to which the patch adheres. As to the third, the term is directed to a capability of the patch, not to an action.

A patch is "substantially flat" when it is flat enough to have the same overall effect on space for packaging and shipping as it does in its original flat configuration. "Substantially flat" is a term of degree that is sufficiently explained in the '999 Patent. The patent describes that "[t]he transdermal patch 18 preferably is flexible to conform to the contours of the user's body or skin, but *initially is flat to reduce space for packaging and shipping.*" col.9 ll.3–5 (emphasis added). As relevant to this term, the patent also explains that "substantially" is used to denote a characteristic or property that, while not complete, has the "same overall result" as if complete. *Id.* at col.5 ll.45–54. Thus, the purpose of the patch's initial flatness is to reduce space for packaging and shipping and it is substantially flat if it has the same overall result as its initial flatness with respect to packaging and shipping.

In the context of the patent's description and claim set, the bending of Claim 15 refers to the bending a patch adhered to a ply experiences when the plies of the pouch are peeled apart. The claimed "resilient" is a term of degree that is defined by a bending that is sufficiently explained in the '999 Patent. The patent explains that the patch "is resilient enough to develop a spring force if it is bent backwardly along with one of the plies." *Id.* at col.9 ll.52–56. And this backward bending of the plies is in the context of the user opening the pouch to extract the patch by "grasp[ing] the opposing tabs 40 and 42 with fingers of opposite hands, and pull[ing] the tabs 40 and 42, and thus the plies 22 and 24." *Id.* at col.9 ll.36–50. "The spring force is sufficient to

cause the patch (together with the liner) to peel away from the ply (that is being held by fingers of the user), resulting in the patch being presented, in a ‘free’ state, for removal by the user from between the plies.” *Id.* at 10 ll.15–19. Thus, the Court understands that the bending of the “bent out of the flat configuration” is due to the bending of the ply to which the patch adheres, and that the patch is “resilient” enough to return to a substantially flat position after such bending.

Finally, the patch of claim 14 is a structure having a particular property (resilient) that gives it the capability to “return to a substantially flat orientation after being bent out of the flat configuration.” The claim is directed to capability, not to the act of bending the patch. *See UltimatePointer, L.L.C. v. Nintendo Co.*, 816 F.3d 816, 826 (Fed. Cir. 2016). This is true even if the patch must be bent to determine if it has the capability of returning to a substantially flat orientation after being bent.

Accordingly, the Court holds that this term does not render any claim indefinite and construes it as follows:

- “substantially flat orientation” means “orientation that would allow the patch to fit in the same shipping/packaging space as when in its original orientation”; and
- “bent out of the flat configuration” means “bent out of the flat configuration by the adhesive force binding the patch to the ply which is bent.”

**D. “the first and the second plies each being separable along the seal”**

<b>Disputed Term</b>	<b>Plaintiff’s Proposed Construction</b>	<b>Defendant’s Proposed Construction</b>
“the first and the second plies each being separable along the seal” <ul style="list-style-type: none"> <li>• ’999 Patent Claims 1, 14</li> </ul>	Plain and ordinary meaning.	“the first and second plies both come apart at the seal”

### **The Parties' Positions**

Plaintiff submits that this term is readily understood by one of ordinary skill in the art and by lay person alike, and therefore does not need to be construed. (Dkt. No. 46 at 24). Plaintiff argues that Defendant's proposed construction would improperly change the scope of the claims, not clarify them. (*Id.* at 25). Specifically, Plaintiff contends that "separable along the seal" is not the same as "come apart at the seal" as Defendant proposes. (*Id.*). Plaintiff argues that such a redrafting threatens to inject a method step in the apparatus claims that requires the plies "come apart" as opposed to having the property that they are "separable." (*Id.*).

Defendant responds that the "invention requires both plies separate entirely from each other at the seal, or at the point where both plies are in contact with each other." (Dkt. No. 49 at 29).

In addition to the claims themselves, Defendant cites the following **intrinsic evidence** to support its position: '999 Patent col.5 ll.21–22, col.5 ll.24–39.

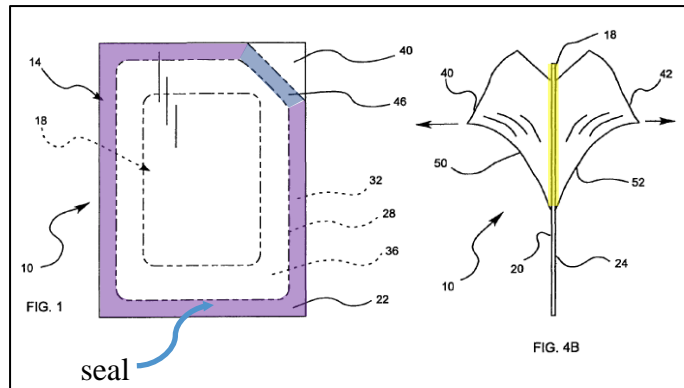
Plaintiff replies that this term simply explains that the plies are able to be separated from each other along the seal. (Dkt. No. 51 at 11). Plaintiff further replies the '999 Patent's claims and description are clear that the seal need only extend around a portion of the perimeters of the plies, and that the plies may be separated along the seal other than being separated entirely from each other, as Defendant contends. (*Id.*).

Plaintiff cites further **intrinsic evidence** to support its position: '999 Patent col.2 ll.33–35, figs.3, 4A, 4B, 5.

## Analysis

The issue here is whether the plies must completely separate from each other in order to be “separable along the seal.” They do not. Neither Defendant nor Plaintiff objected to the Court’s construction at the hearing.

Figure 1 of the ’999 Patent, reproduced here and annotated by the Court, depicts an embodiment in which the seal (32, in purple) extends around the entire perimeter of the plies. ’999 Patent col.8 ll.60–62, fig.1. Figure 4B,



reproduced here and annotated by the Court, depicts the Figure 1 embodiment in an open position—in which *portions* of the plies (20, 24) are “separated along the seal.” *Id.* at col.3 ll.24–26, col.9 ll.29–34. There is no reasonable argument that “separable along the seal” means anything other than “capable of being separated along the seal.” And the patent clearly describes that the plies are separated along the seal to “open the enclosure and expose the patch,” as recited in the claim, when portions of the plies are separated along the seal.

Accordingly, the Court rejects Defendant’s “both come apart at the seal” limitation and determines that the term has its plain and ordinary meaning and does not need to be further construed.

## **V. CONCLUSION**

The Court adopts the above constructions set forth in this opinion for the disputed and agreed terms of the ’999 Patent. The parties are ordered that they may not refer, directly or indirectly, to each other’s claim construction positions in the presence of the jury. Likewise, the

parties are ordered to refrain from mentioning any portion of this opinion, other than the actual definitions adopted by the Court, in the presence of the jury. Any reference to claim construction proceedings is limited to informing the jury of the definitions adopted by the Court.

**SIGNED this 9th day of July, 2016.**

  
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ROY S. PAYNE  
UNITED STATES MAGISTRATE JUDGE